Individual Safety Report
3724790-6-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

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Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only
Triage unit sequence # 143722

Patient information

1. Patient identifier	2. Age at time of event: or Date of birth:	3. Sex	4. Weight
[redacted]5311 In confidence	9/16/29	☐ female ☒ male	____ lbs or ____ kgs

B. Adverse event or product problem

1. ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mo/day/yr) ____
- ☒ life-threatening
- ☒ hospitalization – initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☒ required intervention to prevent permanent impairment/damage
- ☐ other: ____

3. Date of event (mo/day/yr): 1/11/01

4. Date of this report (mo/day/yr): 3/7/01

5. Describe event or problem

71 YOM adm on 12/23/00 with right sided weakness and found to have ICH and required ventriculostomy. Pt started on acetaminophen 650mg po q4h and 650mg po q6pm. Pt had received between 1800mg-3500mg/day for approximately 12 days. Pt noted to have increased LFTs and obstructive picture. Pt had complicated course of apnea requiring intubation, UTI, cheyne-stokes breathing, and acute hepatic failure. GI consulted: decision was made to start pt on n-acetylcysteine, mixed hepatocellular/cholestatic picture. GI unclear if it was secondary to PEG, septic picture or acetaminophen. Pt given Vit K 1mg for INR-13

6. Relevant tests/laboratory data, including dates

1/11 APAP < 10

1/19 Tbili = 1.6, Alk Phos = 367, GGT = 356, AST = 34, ALT = 114

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

NKDA

PMH: HTN, NIDDM

CTW 143722

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Acetaminophen APAP
- #2 Acetaminophen APAP

2. Dose, frequency & route used
- #1 650mg po q4hr
- #2 650mg po q6 pm

3. Therapy dates (if unknown, give duration) from/to (or best estimate)
- #1 12/30/00 - 1/11/01
- #2 12/30/00 - 1/11/01

4. Diagnosis for use (indication)
- #1 Fever/Pain
- #2

5. Event abated after use stopped or dose reduced
- #1 ☒ yes ☐ no ☐ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☒ doesn't apply
- #2 ☐ yes ☐ no ☐ doesn't apply

9. NDC # (for product problems only)
- -
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

(carvedilol, SSI, sucralfate, TPN) Piperacillin, Enalapril

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address DSS MAY 18 2001

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other: ____

5. Expiration date (mo/day/yr)

6. model # RECEIVED
catalog # MAY 18 2001
serial # MEDWATCH CTU
lot #
other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #
[redacted]

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☒ user facility
- ☐ distributor

5. If you do NOT want your identity disclosed to the manufacturer, place an " X " in this box. ☒

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787 or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/93)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event